DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 28, 2015

Pasture Pharma Pte, Ltd
C/O Ms. Sarah Hassan
US MedPharm
38129 Spring Canyon Drive
Murrieta, CA 92563

Re: K141876
Trade/Device Name: Pasture F550S Surgical N95 Respirator, Pasture F550CS Surgical N95 Respirator, Pasture A520S Surgical N95 Respirator, Pasture A520CS Surgical N95 Respirator, Pasture E520S Surgical N95 Respirator, Pasture E520CS Surgical N95 Respirator
Regulation Number: 21 CFR 878.4040
Regulation Name: Surgical Apparel
Regulatory Class: II
Product Code: MSH
Dated: October 15, 2015
Received: October 16, 2015

Dear Ms. Hassan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin Keith, M.S.
Director
Division of Anesthesiology,
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141876

Device Name
Pasture F550S Surgical N95 Respirator, Pasture F550CS Surgical N95 Respirator, Pasture A520S Surgical N95 Respirator, Pasture A520CS Surgical N95 Respirator, Pasture E520S Surgical N95 Respirator, Pasture E520CS Surgical N95 Respirator

Indications for Use *(Describe)*
Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS is a NIOSH certified N95 respirator, and is indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) SUMMARY

This 510(K) Summary is being submitted in accordance with requirements of 21 CFR 807.92(c)

The assigned 510(k) number is: K141876

Submitter Name and Address:

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Date Prepared: October 27, 2015

Proprietary Name:

Pasture F550S Surgical N95 Respirator, Pasture F550CS Surgical N95 Respirator, Pasture A520S Surgical N95 Respirator, Pasture A520CS Surgical N95 Respirator, Pasture E520S Surgical N95 Respirator, Pasture E520CS Surgical N95 Respirator

Common name: Surgical N95 NIOSH certified Respirator

Device Classification and Product Code

Classification Name: Surgical Apparel

Regulation: 21 CFR §878.4040

Class: Class II

Classification panel: General and Plastic Surgery

Product Code: MSH

Predicate Device: K070139

WILLSON ONE-FIT HEALTHCARE PARTICLE RESPIRATOR AND SURGICAL MASK, HC-NB095

SURVIVAIR, INC

Intended Use:

Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS is a NIOSH certified N95 respirator, and is indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.

Device Description:

Pasture F550S and Pasture F550CS respirators are disposable duck bill shaped N95 respirators with NIOSH certification number TC-84A-7504. They contain 5 layers composed of polypropylene, with a nose cushion, a synthetic elastic loop or strap, and a nosepiece which is the combination of zinc wires and embedded polyester inside of layers. F550CS is the same respirator as the F550S, but F550CS contains an adjustable buckle on the headband.

Pasture A520S and Pasture A520CS respirators are cup shaped N95 respirators with NIOSH certification number TC-84A-7454. They contain 4 layers composed of polypropylene with a synthetic elastic loop or a strap. A520CS is the same respirator as the A520S, but A520CS contains an adjustable buckle on the headband.

Pasture E520S and Pasture E520CS respirators are cup shaped N95 respirators with NIOSH certification number TC-84A-7453. They contain 4 layers composed of polypropylene with a

nose cushion, synthetic elastic loop or strap, and an aluminum nosepiece. E520CS is the same respirator as E520S, but E520CS contains an adjustable buckle on the headband.

Description	**Predicate K070139**	**Pasture F550S**	**Pasture F550CS**	**Pasture A520S**	**Pasture A520CS**	**Pasture E520S**	**Pasture E520CS**
NIOSH certification number	N95 TC-84A-4516	N95 TC-84A-7504	N95 TC-84A-7504	N95 TC-84A-7454	N95 TC-84A-7454	N95 TC-84A-7453	N95 TC-84A-7453
Outer layer	Polyester	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond
Filter Media	Polypropylene	Polypropylene Meltblown	Polypropylene Meltblown	Polypropylene Meltblown	Polypropylene Meltblown	Polypropylene Meltblown	Polypropylene Meltblown
Inner layer	Polypropylene	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond	Polypropylene Spunbond
Nose Piece	Not Applicable	combination of zinc wires and embedded polyester	combination of zinc wires and embedded polyester	Not Applicable	Not Applicable	aluminum	aluminum
Ear Attachment	synthetic elastic	synthetic elastic	synthetic elastic	synthetic elastic	synthetic elastic	synthetic elastic	synthetic elastic
Respirator style	cup shaped	duck bill shaped	duck bill shaped	cup shaped	cup shaped	cup shaped	cup shaped
Design features	3 layers molded-cone with filter web in the middle	5 layers of non-woven fiber containing filter web in the middle	5 layers of non-woven fiber containing filter web in the middle	4 layers molded-cone with filter web in the middle	4 layers molded-cone with filter web in the middle	4 layers molded-cone with filter web in the middle	4 layers molded-cone with filter web in the middle
Adjustable buckle	Not Applicable		Acrylonitrile Butadiene Styrene		Acrylonitrile Butadiene Styrene		Acrylonitrile Butadiene Styrene

Test	**K070139**	**F550S** **F550CS**	**A520S** **A520CS**	**E520S** **E520CS**
NIOSH Certification	N95 TC-84A-4516	N95 TC-84A-7504	N95 TC-84A-7454	N95 TC-84A-7453
Fluid Resistance (ASTM F1862)	Not available	Pass 120mmHg	Pass 120mmHg	Pass 160mmHg
Flammability (16 CFR 1610)	Not available	Class 1	Class 1	Class 1
In vitro cytotoxicity	Not available	Non-cytotoxic under conditions of study	Non-cytotoxic under conditions of study	Non-cytotoxic under conditions of study
Sensitization	Not available	Non-sensitizer under conditions of study	Non-sensitizer under conditions of study	Non-sensitizer under conditions of study
Irritation	Not available	Non-irritant under conditions of study	Non-irritant under conditions of study	Non-irritant under conditions of study
Size		90±3*200±3*95±3mm	150±3*130±3*60±3mm	140±3*125±3*50±3mm
Sterility	Non-sterile Single use	Non-sterile Single use	Non-sterile Single use	Non-sterile Single use
Indication for Use	Please see below *1	Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS is a NIOSH certified N95 respirator, and is indicated to be used by the healthcare personnel during procedures to protect both the patient and the healthcare personnel from the transfer of microorganisms, body fluids, and particulate material.		

*1 The Willson® ONE-Fit™ HC-NB095 Healthcare Particulate Respirator and Surgical Mask is a NIOSH-approved N95 single use respirator intended for use by healthcare personnel during medical/ surgical procedures to protect both the wearer against the spatter of blood and other potentially infectious materials and reducing the transfer of microorganisms and other airborne particulate matter.

Comparison to Predicated Device:

Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S and Pasture E520CS respirators are substantially equivalent to WILLSON ONE-FIT HEALTHCARE PARTICLE RESPIRATOR AND SURGICAL MASK, HC-NB095.

Performance Testing

Test Performed	**Result**
Fluid Resistance	The Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS met the requirements of ASTM F1862.
Flammability	The Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS met the requirements of 16 CFR 1610.
Particulate Filtration Efficiency	NIOSH Certification: TC-84A-7504 (F550S and F550CS) NIOSH Certification: TC-84A-7454 (A520S and A520CS) NIOSH Certification: TC-84A-7453 (E520S and E520CS)
Bacterial Filtration Efficiency	NIOSH Certification: TC-84A-7504 (F550S and F550CS) NIOSH Certification: TC-84A-7454 (A520S and A520CS) NIOSH Certification: TC-84A-7453 (E520S and E520CS)
Differential Pressure	NIOSH Certification: TC-84A-7504 (F550S and F550CS) NIOSH Certification: TC-84A-7454 (A520S and A520CS) NIOSH Certification: TC-84A-7453 (E520S and E520CS)

Cytotoxicity	The Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS were non-cytotoxic under the conditions of the study.
Irritation	The Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS were non-irritating under the conditions of the study.
Sensitization	The Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S, and Pasture E520CS were non-sensitizing under the conditions of the study.

Conclusions:

The test data submitted in this submission demonstrate that the subject device is as safe and as effective as the predicate and technological characteristics do not raise any new questions of safety and effectiveness. Pasture F550S, Pasture F550CS, Pasture A520S, Pasture A520CS, Pasture E520S and Pasture E520CS are substantially equivalent to the predicate device cleared in K070139.